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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,292	04/10/2001	Alexey Ryazanov	601-1-098CIP	8327
23565	7590	11/26/2004	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/832,292	Applicant(s) RYAZANOV, ALEXEY	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 14-17 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claims 4, 5, 14 and 16, in the paper of 9/3/2004, is acknowledged and has been entered. Claims 4, 5 and 14-17 are at issue and are present for examination.

Applicants' arguments filed on 9/3/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

The granting of applicants claim of priority for the DNA sequence of SEQ ID NO: 34 to the instant application, filed 4/10/2001, remains proper, as there is no support for this sequence in application Serial No. 09/623,131.

Applicants comments in the paper filed 9/3/2004 regarding the above claim of priority are acknowledged in full, however, not found persuasive. As stated previously and above, priority for the DNA sequence of SEQ ID NO: 34 is granted only to the instant application, filed 4/10/2001. Applicants arguments regarding this issue appear to be directed to the issue of enablement. The examiner is not questioning whether or not "the skilled artisan could readily and without undue experimentation isolate and determine the remaining nucleic acid and polypeptide sequence of the human heart alpha kinase, particularly utilizing the human heart alpha kinase cDNA in possession of the inventors at the time of filing of the '131 application", but rather the examiner is

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pointing out that applicants do not have support for the sequence of SEQ ID NO: 34 in the '131 application.

Claim Objections

Claim 5 is objected to because of the following informalities:

Claim 5 is dependent on rejected claim 4.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it previously applied to previous claims 4 and 14-17. In response to this rejection, applicants have amended claims 4, 14 and 16 and argue this rejection as it applies to the amended claims.

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Within applicants traversal of the current rejection, applicants point out that the terms "naturally occurring" are not present or cited in the current claim language of claims 4 and 14-17. Applicants further acknowledge and agree that the claimed genus encompasses naturally occurring allelic variants of nucleic acids that encode SEQ ID NO: 35, but is not limited solely to those sequences. Applicants submit that applicants characterize and claim the named heart alpha kinase by its sequence, its natural expression characteristics and by its alpha kinase activity and that each of these characteristics are clear and readily determinable and testable by the skilled artisan. Applicants argument has been considered in full, however, found non-persuasive. The rejection is maintained on the basis that in addition to the above pointed out characteristics, applicants claims further stipulate that the encoded alpha kinase be a "mammalian" alpha kinase and that while the claim does not recite "naturally occurring", the claimed mammalian alpha kinases are a subset of naturally occurring alpha kinases. Thus while the claims do not specifically recite naturally occurring, they are drawn to the naturally occurring subgenus of mammalian alpha kinases and subject to any issues associated with such claims.

Thus as previously stated, in the instant specification, a single nucleic acid encoding an alpha kinase is fully described in the form of SEQ ID NO:34, wherein the nucleic acid encodes a protein having alpha kinase activity. This description also adequately describes a genus, within the sequence identity (hybridization) limitations of the instant claims, of nucleic acids encoding proteins having this particular function. Those sequences that are "mammalian" or "naturally occurring" are a subset of this

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genus. The specification does not adequately describe this subset according to its structure so that one of skill in the art would be able to predict naturally occurring sequences, particularly in view of the larger genus that includes both naturally and "manufactured" sequences. Therefore, the instant claims are not adequately described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 4 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with a DNA molecule comprising SEQ ID NO: 34, does not reasonably provide enablement for any host cell transformed with any DNA sequences which hybridizes under standard conditions to the DNA sequence of SEQ ID NO: 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it previously applied to previous claims 4 and 14-17. In response to this rejection, applicants have amended claims 4, 14 and 16 and argue this rejection as it applies to the amended claims.

Applicants traverse this rejection on the basis that applicants submit that applicants specification clearly enables the skilled artisan to make and/or use the host cells as claimed on the basis that the isolation of hybridizing sequences is straightforward and readily performed by the skilled artisan, and that while some

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experimentation is necessary, such is not undue experimentation. Applicants submit that using the described SEQ ID NO: 34, the skilled artisan could readily isolate, make and test other members of the genus of sequences hybridizing thereto under standard conditions.

Applicants argument has been considered in full, however found nonpersuasive, on the following basis. As previously stated, the instant specification teaches SEQ ID NO:35, an alpha kinase expressed in the mammalian heart, and SEQ ID NO:34 encoding SEQ ID NO:35. The art includes few examples of mammalian alpha kinases expressed in the heart. The art fully enables any DNA encoding SEQ ID NO:35, based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other nucleic acids encoding mammalian alpha kinases expressed in the heart using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the nucleic acids within the scope of the claims because the ability to find a nucleic acid which encodes a mammalian alpha kinase which is expressed in the heart, which is structurally related to SEQ ID NO:34, is not equivalent to the ability to make the claimed genus of nucleic acids as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its alpha kinase and heart expression is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

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While applicants point out various portions of the specification, which help enable the claims, applicants have not addressed the above issue (i.e. particular residues whose encoding is important within the disclosed sequence so that its alpha kinase and heart expression is maintained).

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those nucleic acid molecules having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
11/22/2004